

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 47-R-0010 CUSTOMER NO. 1550

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)**

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)  
SCHERING-PLOUGH ANIMAL HEALTH, CORP  
P O BOX 3113  
OMAHA, NE 68103

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

SCHERING-PLOUGH ANIMAL HEALTH

(b)(2)High, (b)(7)f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

| A.                     | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs                | 18  | 682   | 68   | 4  | 754                                       |
| 5. Cats                | 12  | 527   | 52   | 3  | 582                                       |
| 6. Guinea Pigs         | 4   | 490   | 429  | 51   | 970                                       |
| 7. Hamsters            | 502   | 3714  | 1593   | 1186   | 6493                                      |
| 8. Rabbits             | 23  | 387   | 144  |  | 531                                       |
| 9. Non-Human Primates  |   |   |  |  |   |
| 10. Sheep              |   |   |  |  |   |
| 11. Pigs               |   |   |  |  |   |
| 12. Other Farm Animals |   |   |  |  |   |
| 13. Other Animals      |   |   |  |  |   |
| Ferrets                | 1   | 130   |  |  | 130                                       |
| Mink                   | 24  | 216   | 5  | 60   | 281                                       |

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the institution's Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)c

10/29/2007

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number:

47-R-0010

2/3. Species (common name) & Number of animals used in this study:

Dogs (4)

4. Explain the procedure producing pain and/or distress.

These dogs became ill following a (b)(4) Clinical signs of this challenge (b)(4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Pain and distress relieving medications were not utilized since they would mask the effects of (b)(4) such as (b)(4). These effects or clinical signs were closely monitored and utilized as sensitive endpoints. Unfortunately due to the rapid progression of the disease four dogs became moribund prior to intervention. Clinical signs of this (b)(4) material were evaluated and recorded carefully to help further define and improve our sensitive endpoints. These refined endpoints will be applied to future studies.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

(b)(4)

CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addressees, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 47-R-0010

2/3. Species (common name) & Number of animals used in this study:

Cats (3)

4. Explain the procedure producing pain and/or distress.

These cats became ill following (b)(4) Clinical signs of this (b)(4) include (b)(4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Pain and distress relieving medications were not utilized since they would mask the effects of (b)(4) such as (b)(4). These effects or clinical signs were closely monitored and utilized as sensitive endpoints. Unfortunately due to the rapid progression of the disease three cats became moribund prior to intervention. Clinical signs of this (b)(4) (b)(4) were evaluated and recorded carefully to help further define and improve our sensitive endpoints. These refined endpoints will be applied to future studies.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

(b)(4)

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 47-R-0010

2/3. Species (common name) & Number of animals used in this study:

Hamsters (1186)

4. Explain the procedure producing pain and/or distress.

These hamsters were used for [REDACTED] (b)(4). The [REDACTED] (b)(4) was performed according to federal regulations. The hamsters experience [REDACTED] (b)(4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The tests are [REDACTED] (b)(4), required by regulation for the release of each [REDACTED] (b)(4). The effects of pain medication on the length and severity of the disease is not known, and thus would invalidate the scientific value of the [REDACTED] (USDA/CVB, private communication). For this reason neither our company nor the USDA/CVB uses any substances to reduce pain and distress. The standard test is obligatory for release of [REDACTED] (b)(4) since a validated USDA/CVB alternative is not currently available for the current test. Sensitive endpoints have been applied successfully to these tests as allowed by USDA Notice 04-09. This has reduced the suffering that this test causes.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: [REDACTED] (b)(4) CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 47-R-0010

2/3. Species (common name) & Number of animals used in this study:

Mink (60)

4. Explain the procedure producing pain and/or distress.

These mink were utilized in a (b)(4) The animals experienced (b)(4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Tests of the (b)(4) were conducted according to a USDA-mandated method. The (b)(4) (b)(4) is required by regulation as a proof of (b)(4) to be conducted on each serial of vaccine produced. The progression of the disease is rapid and the animals experienced (b)(4) For the required (b)(4), the progression of the disease would likely be affected by the use of analgesic medication. For this reason neither our company nor USDA/CVB uses any substances to reduce pain and distress. It is not known how the use of pain medication would affect the length and severity of the disease. Therefore the use of these drugs would invalidate (according to private communication with the USDA/CVB) the scientific value of the (b)(4) required by the test. Lack of confidence in this test would render the test itself useless for judging (b)(4) APHIS-USDA-CVB is engaged in developing in (b)(4) alternatives for products that require animal testing for product release. Until validated USDA-CVB approved alternatives are available, the standard tests are obligatory. No alternatives exist at this time.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: (b)(4) CFR: